

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

Comparison of the Effect of Hot Water Bag and Hot Water Shower on the Pain and Active Phase of Pregnancy in Primiparous Women

Protocol summary

Study aim

Comparison of the effect of warm water bag and hot water shower on pain and duration of first stage of labor in primipara women

Design

The study consisted of two groups of 36 people (warm water bag, warm shower) that were randomly divided into two groups.

Settings and conduct

This study is done in delivery unit of Shahidan Mobini hospital in Sabzevar. Mothers, after obtaining informed consent and having the conditions for entering the study, are placed in two groups of hot water and warm water showers. After receiving the intervention, the pain and duration of maternal delivery are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age between 37 and 42 weeks, First pregnancy, The spontaneous onset of labor pains, No record of mental and medical sickness, Normal heart rate of fetus, Single pregnancy, No addiction to cigarette, drugs, and alcohol, Having no detectable barriers to normal delivery, No record of infertility
Exclusion criteria: Having contraindications to normal delivery, Consumption of any tranquilizer or drug within 48 hours before the start of the study

Intervention groups

In the warm shower group; warm shower is performed in 4 cm of dilatation, and the researcher is assisted by a full body shower for 15 minutes in a 7 cm dilatation. In the hot water bag in the active phase of labor (4 centimeters up) and once in a 7-cm stage, a warm water bag is in the waist, fundus, or under the abdomen. The duration of using a warm water bag is based on the book of principles and techniques of nursing every 20 minutes.

Main outcome variables

Active phase length of labor Labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151005024371N3**

Registration date: **2019-02-05, 1397/11/16**

Registration timing: **retrospective**

Last update: **2019-02-05, 1397/11/16**

Update count: **0**

Registration date

2019-02-05, 1397/11/16

Registrant information

Name

Mozhdeh Navi Nezhad

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4423 3808

Email address

navinm921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Hot Water Bag and Hot Water Shower on the Pain and Active Phase of Pregnancy in Primiparous Women

Public title

Comparison of the Effect of Hot Water Bag and Hot Water Shower on the Pain and Active Phase of Pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age between 37 and 42 weeks First pregnancy The spontaneous onset of labor pains No record of mental and medical sickness Normal heart rate of fetus Single pregnancy No addiction to cigarette, drugs, and alcohol Having no detectable barriers to normal delivery No record of infertility

Exclusion criteria:

Problems and skin ulcers Consumption of any tranquilizer or drug within 48 hours before the start of the study Mother's lack of cooperation

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method: Using random allocation using variable blocks. Two groups of four blocks (AABB-BBAA-ABAB-BABA-ABBA-BAAB) were used. The subjects were divided into two groups of intervention and control in order to determine the number of subjects in equal groups (36 in each group). Control group A and intervention group B were called. To determine the order of entry of individuals into groups, random numbers and closed packet were used.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Sabzevar Medical Sciences

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Kashfi Street

City

Khorasan Razavi

Province

Razavi Khorasan

Postal code

9613883778

Approval date

2018-08-21, 1397/05/30

Ethics committee reference number

IR.MEDSAB.REC.1397.026

Health conditions studied**1****Description of health condition studied**

Natural delivery

ICD-10 code

O75.0

ICD-10 code description

Maternal distress during labour and delivery

Primary outcomes**1****Description**

Labor pain severity

Timepoint

Before intervention and 30 minutes after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Duration of active phase of labor

Timepoint

From 4 cm dilation to full dilation

Method of measurement

Partograph form in terms of minute

Intervention groups**1****Description**

"Hot water shower group": Hot shower will be firstly applied for 20 minutes at 4 cm dilation and then at 7 cm dilation. Main outcome measures include the pain severity and the duration of active phase that will be measured respectively by Visual Analogue Scale (VAS) and partograph form.

Category

Treatment - Other

2

Description

"Warm water bag group": Warm water bag will be firstly applied for 20 will be firstly applied for 20 minutes at 4 cm dilation and then at 7 cm dilation. Warm water bag will be used in the waist, fundus or abdomen. Main outcome measures include the pain severity and the duration of active phase that will be measured respectively by Visual Analogue Scale (VAS) and partograph form.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobini hospital

Full name of responsible person

Mitra Eftekhari Yazdi

Street address

Kashfi Street

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9613883778

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navinm921@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mitra Eftekhari Yazdi

Position

Expert physician

Latest degree

Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data relating to the main variables of the research is reported after being unidentifiable

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the article

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Registered at the Clinical Practice Registration Center

From where data/document is obtainable

Responsible for studying Contact with mailbox
NAVINM921@MUMS.AC.IR

What processes are involved for a request to access data/document

Send an email requesting data to the study author by email NAVINM921@MUMS.AC.IR

Comments